

REMARKS

Claims 40-78 have been canceled without prejudice, and new claims 79-95 have been presented herein. The new claims are supported by the as-filed claims and the as-filed Specification. The incorporation of high stringency conditions is supported by the as-filed Specification at page 24, lines 4-5. None of the amendments made herein constitutes the addition of new matter.

The Formal Drawings

In response to requirements of the Patent and Trademark Office, Applicants provided Formal Drawings for entry into the present application in July 2002. Applicants respectfully request that the Patent Office confirm acceptance of the drawings.

The Requirement for Restriction

The Patent Office has alleged that claims 52, 53 and 60 are directed to an invention which is independent from the invention as originally claimed because the nucleic acids and proteins are structurally and functionally distinct, and thus do not have a shared technical feature. These claims are withdrawn from consideration as directed to a non-elected invention.

Applicants have canceled claims 40-79 and have not incorporated the subject matter of claims 52, 53 and 60 in the claims newly presented herein. However, Applicants respectfully request that with the allowability of the claims specifying SEQ ID NO:10, that the extent of examination be expanded with respect to DNA sequences related to other EcR coding sequences, genetic constructs and host cells.

The Claim Objections

Claims 62, 64 and 65 are objected to as allegedly drawn to a nonelected invention. Applicants respectfully request clarification. In the section of the Office Action related to the requirement for restriction, claims 52, 53 and 60 were alleged to be patentably distinct.

Claims 40-78 have been canceled without prejudice in the present Amendment. The subject matter of claims 62, 64 and 65 has not been presented in the new claims.

The Rejections under 35 U.S.C. 112, first paragraph

Claims 40-51, 54-59 and 68-74 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly not enabled for coding sequences of 60% or greater nucleotide sequence homology to SEQ ID NO:10 or for a bioactive derivative or analog of SEQ ID NO:10. Applicants respectfully traverse this rejection.

In the interest of advancing prosecution and without acquiescing to this rejection, Applicants have presented claims 79-84 and 91-94 to recite those particularly exemplified sequences of SEQ ID NOs:11 and 12. Applicants have presented limited claims (85-90 and 95) reciting sequences having at least 60% or greater sequence identity to SEQ ID NO:10 and to specify that the encoded protein is an ecdysteroid receptor polypeptide which binds ecdysone when said receptor polypeptide is in contact with a USP polypeptide. This limitation was discussed in the personal interview of June 27, 2002, and it was Applicants' understanding at that time that this level of sequence identity would be acceptable to the Patent Office.

In the interest of advancing prosecution and without acquiescing to the rejection, the new claims do not recite "bioactive derivative or analogue." In view of the high level of skill in the relevant art, the well known techniques for identifying sequences with the specified relatedness to the specific sequence, and the readily accessible methods for testing a protein for ligand binding (e.g., ecdysone binding), Applicants respectfully urge that the invention as claimed is adequately enabled by the as-filed Specification, taken with what is well known and readily accessible in the art.

Claims 40-51, 54-59 and 68-74 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly overly broad. Applicants respectfully traverse this rejection.

The Patent Office has alleged that insufficient guidance is provided as to which of the myriad of variant nucleic acids encode polypeptides which will retain the characteristics of EcR. Applicants are said to not disclose any actually or prophetic examples on expected performance parameters of any of the possible muteins of EcR. The Patent Office has further characterized the state of the art as being that "even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function, and that a single amino acid change in a protein's sequence can drastically affect the structure of a protein and the architecture of an entire cell," citing the example of sickle cell anemia.

As stated above, claims 79-84 and 91-94 recite specifically the exemplified sequences set forth in SEQ ID NOs: 11 and 12 in an effort to advance prosecution in this case. With respect to the remaining claims, there are structural and functional limitations in the claims. With respect to claims 85-90 and 95, whether a particular sequence meets the structural limitation is readily determined by sequence comparison, using methodology well known to the art. These claims contain the functional limitation that the polypeptide must bind ecdysone, a representative insect ecdysteroid. Binding is also determined using techniques well known to the art. Proteins which do not, in the appropriate heterodimer, bind ecdysone are outside the metes and bounds of the claims. The application, at page 38, line 23, through page 39, line 2, provides guidance concerning conservative acid substitutions. This is well understood in the art, and variants produced can be tested using techniques well known to the art. Applicants respectfully maintain that the claims are adequately enabled when the Specification is taken together with the knowledge of the art. Applicants respectfully maintain that the claims are adequately enabled when the Specification is taken together with the knowledge of the art.

Claims 40-51, 54-59 and 68-74 have been rejected under 35 U.S.C. 112, first paragraph, with the Patent Office alleging containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention. Applicants respectfully traverse this rejection.

Claims 40-78 have been canceled without prejudice. In the interest of advancing prosecution and without acquiescing to the rejection, new claims 79-84 and 91-94 do not recite percent homology, but rather the specifically exemplified sequences.

It has been alleged that there are genus claims, and that the Specification and claims do not indicate the distinguishing attributes of the genus. With respect to claims 85-90 and 95, Applicants respectfully note that the Specification and claims clearly indicate that the encoded EcR proteins bind ecdysteroids, e.g., ecdysone. The methods for confirming ligand binding in such a situation are well known to the art. The second distinguishing attribute is the structural characterization at least 60% sequence identity with SEQ ID NO:11 or SEQ ID NO:12. In the interest of advancing prosecution, Applicants previously added specific recitation related to ecdysone binding in the claims.

In view of the amendments and the foregoing discussion, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

Allowable Subject Matter

Claims 46-48 are objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims. Applicants have presented new claims limited in accordance with claims 46-48.

Applicants have rewritten these claims to be free of the rejected base claim(s). Allowance is respectfully requested.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

Application No. 09/346,470
Amendment dated April 18, 2003
Response to Office Action of October 21, 2002

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by the a Petition for Extension of Time (three months) and a check in the amount of \$930.00 as required by 37 C.F.R. 1.17. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



Donna M. Ferber
Reg. No. 33,878

GREENLEE, WINNER AND SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone (303) 499-8080
Facsimile: (303) 499-8089
Email: winner@greenwin.com

Attorney docket No. 53-99
bmk: April 21, 2003